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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/618,623	07/18/2000	Richard W. Gross	15060-0004	9309

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EXAMINER	
PAK, YONG D	
ART UNIT	PAPER NUMBER
1652	11

DATE MAILED: 05/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No. 09/618,623	Applicant(s) GROSS ET AL.	
	Examiner Yong Pak	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *6 and 9-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The response to the Restriction Requirement filed on March 18, 2002 has been entered.

Claims 1-37 are pending.

The preliminary amendment filed on December 14, 2001, amending the specification, has not been entered. The amendment has not been entered because Table 1 does not exist on page 16 of the specification and there are no primer sequences on page 16 of the specification.

Election/Restrictions

Applicant's election with traverse of Group I of SEQ ID NO:3 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that examinations of Inventions I-IV and VII-VIII would be searched in class 435 and do not require an undue burden on the examiner. This is not found persuasive because the inventions were classified under the most comprehensive class. Because of the recognized divergent subject matter between I-IV and VII-VIII, an unduly extensive and burdensome search is required for Invention II-IV and VII-VIII that is not required for Invention I.

Also, the traversal is on the ground(s) that SEQ ID NO:1-6 are not separate but related molecules in that they all attribute to one molecule, the phospholipase A2. This is not found persuasive because the specification states that SEQ ID NO:3 constitutes the cDNA of the coding region and SEQ ID NO:1 is the encoded polypeptide and SEQ

ID NO:4 constitutes the cDNA of the coding region of another variant and SEQ ID NO:2 is the encoded polypeptide (page 4 of the specification). Therefore, the polynucleotide sequences encoding variant phospholipase A2 polypeptides have different structure, functions and substrate specificities.

Applicants also traverse on the grounds that the antisense of Inventions V-VI and the antibody of Invention IX are not patentably distinct from Invention I. This is not found persuasive because a DNA, an antisense and an antibody are different compounds, each with its own chemical structure and function and they have different utilities.

Applicants also traverse on the grounds that the methods of Inventions X-XVI are all methods of characterization of the polypeptide and not materially different methods of employing different products and the effects and utilities of these methods are all directly related to characterization of the polypeptide. This is not found persuasive because even thought the methods relate to the phospholipase, the methods are patentably distinct from each other for employing different products and having different utilities (see Paper 7).

Claims 6 and 9-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The sequence Rules 1.821 (c) requires a sequence identifier for each sequence. However, the same amino acid sequence is identified by different sequence identifier. SEQ ID NOs: 1 and 5 are 100% identical.

In addition, in the specification, SEQ ID NO:2 is referred as a polypeptide but in the Sequence Listing, SEQ ID NO:2 is a polynucleotide sequence (on page 4, 2nd paragraph of the specification and on pages 4-7 of the Sequence Listing).

Claim Objections

Claims 3, 6-8 are objected for being drawn to non-elected products, SEQ ID NOs: 4-6 and DNA encoding SEQ ID NO:2. In addition, in claim 3, SEQ ID NO:2 is referred as a polypeptide but in the Sequence Listing, SEQ ID NO:2 is a polynucleotide sequence.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 7-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to a polynucleotide encoding a phospholipase $A_{2\gamma}$ and claim 2 limits claim 1 to a phospholipase $A_{2\gamma}$ that catalyzes cleave of fatty acids from the sn-2 position of phospholipids. Therefore, these claims encompass a genus of a polynucleotide encoding a phospholipase $A_{2\gamma}$ of any structure and from any source. Applicant discloses a phospholipase $A_{2\gamma}$ of SEQ ID NO:1. A description of only one member of this genus is not representative of the variants of the genus. The specification does not disclose the identifying characteristics, which would allow one to recognize a nucleic acid molecule as being a phospholipase $A_{2\gamma}$.

Claim 7 is drawn to a polynucleotide having at least about 90% sequence identity with SEQ ID NO:3 with no limitations to the function of the encoded polypeptide. Therefore, this claim is drawn to a large variable genus of polynucleotides encoding polypeptides having unknown activity or inactive variants. Applicants only describe a phospholipase $A_{2\gamma}$ of SEQ ID NO:1. The specification does not describe the function of all the polypeptide sequences derived or modified from SEQ ID NO:1 and therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims. Therefore, applicants fail to describe representative species by identifying characteristics or structural properties other than comprising of SEQ ID NO:3.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 1-5 and 7-8.

Claims1-5 and 7-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide encoding the phospholipase $A_{2\gamma}$ of SEQ ID NO: 1, does not reasonably provide enablement for polypeptides with structures different from SEQ ID NO:1. The specification does not reasonably provide enablement for variant polypeptides of SEQ ID NO: 1 having unknown function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification teaches how to make and use the polynucleotide encoding the phospholipase $A_{2\gamma}$ of SEQ ID NO:1. Applicants do not teach which amino acids of SEQ ID NO:1 can be modified without affecting the functional properties of the polypeptide. The specification does teach how to make variants of SEQ ID NO:1 having unknown function. However, the function of a polypeptide can not be predicted from its structure and the specification does not teach how to use polypeptides with unknown function.

Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

The specification, which places no limitation on the structure of the polypeptides as discussed above, does not support the broad scope of the claims because the specification does **not** establish: (A) regions of the phospholipase $A_{2\gamma}$ structure which may be modified without effecting its activity; (B) the general tolerance of to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Therefore, one of ordinary skill would require guidance in order to make polynucleotides encoding polypeptides with structures different from SEQ ID NO:1 having phospholipase $A_{2\gamma}$ activity and how to use variant polypeptides of SEQ ID NO:1 having unknown function in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 7-8 are rejected under 35 U.S.C. 102(a) as being anticipated by Mancuso et al. need due

Mancuso et al. (form PTO-892) teach a nucleic acid molecule encoding a phospholipase $A_{2\gamma}$ that is 100% identical to SEQ ID NO:1 and comprises of SEQ ID NO:3 (Figure 5, page 9942). Mancuso et al. also teach a vector comprising the nucleic acid molecule and a host cell comprising said vector (Pages 9938-9939). Therefore, the teachings of Mancuso et al. anticipates claims 1-5 and 7-8.

Claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al.

Jones et al. U.S. Patent No. 5,466,595 (form PTO-892) teach a nucleic acid molecule encoding a phospholipase A_2 that catalyzes the *sn*-2 position of phospholipids (Columns 15-22 and Column 3, line 39 through Column 4, line 19). Jones et al. also teach a vector comprising the nucleic acid molecule and a host cell comprising said

vector (Columns 13-14 and claims 1-9). Therefore, the teachings of Jones et al. anticipates claims 1-2 and 4-5.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-746-7240 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

May 2, 2002

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